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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,685	11/12/2003	James F. McGuckin JR.	1238DIV	7009
7590 NEIL D. GERSHON REX MEDICAL 1011 HIGH RIDGE RD Stamford, CT 06905		05/01/2007	EXAMINER SCHILLINGER, ANN M	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/706,685	MCGUCKIN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Ann Schillinger	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 November 2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 and 25-30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-17 and 25-30 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 12 November 2003 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/24/04, 9/6/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claim 25 recites the limitation "the longitudinal axis" in line 5. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 8-12, 15, 16, 25, 27, 28, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (US Pat. No. 5840081). Anderson et al. discloses the following of claim 1: a vascular device comprising a plurality of vessel engaging members (4, 7, 8, 14) and a valve (6), the device movable from a collapsed insertion position having a first diameter to a second expanded position having a second diameter larger than the first diameter (see Figures 5, 6), the plurality of vessel engaging members extending outwardly from the device for securely engaging the internal wall of a vessel upon expansion of the device to the second expanded position (see Figure 4), the vessel engaging members pulling the internal wall of the vessel radially inwardly upon movement of the device from the second expanded position toward a first expanded position having a third diameter, the third diameter being greater than the first diameter and less than the second diameter (see Figure 7), and in the first expanded position the valve movable between an open position to allow blood flow therethrough to a closed position to prevent blood flow (col. 2, lines 38-65).

Anderson et al. discloses the following of claim 5: the vascular device of claim 1, wherein the valve is substantially conical in shape (see Figure 3).

Anderson et al. discloses the following of claim 6: the vascular device of claim 5, wherein a longitudinal axis of the valve is offset from a longitudinal axis of the vascular device (see Figure 9 where a straight axis through the vessel will be different from a straight axis through the device).

Anderson et al. discloses the following of claim 8: the vascular device of claim 1, wherein the valve has a proximal opening (side nearest element 4) and a distal opening (side nearest element 25), and a reinforcement ring (25) adjacent the distal opening.

Anderson et al. discloses the following of claim 9: the vascular device of claim 1, wherein the valve is attached to a distal end of the vascular device to extend downstream of the device when positioned within a patient (see Figure 3).

Anderson et al. discloses the following of claim 10: the vascular device of claim 1, wherein the valve is attached to a proximal end of the vascular device to extend within a central portion of the device when positioned within a patient (col. 6, line 64 through col. 7, line 8).

Anderson et al. discloses the following of claim 11: the vascular device of claim 1, wherein the valve is a duckbill valve configuration (see Figure 2).

Anderson et al. discloses the following of claim 12: a vascular system comprising: a balloon catheter (11) having an elongated shaft and an expandable balloon (13); a vascular device (4, 7, 8) mounted over the expandable balloon having a first position and a second expanded position, the vascular device expandable to an expanded position to engage the vessel walls and returnable substantially to the first position to bring the walls radially inwardly (see

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Figures 5-7); and a valve (9) connected to the vascular device and movable between a closed position to prevent blood flow and an open position to allow blood flow therethrough (col. 3, lines 10-17).

Anderson et al. discloses the following of claim 15: the vascular system of claim 12, wherein the device is comprises stainless steel (col. 4, lines 66-67) and the balloon expands the device below its elastic limit to allow the device to return to the first position (col. 5, lines 28-56).

Anderson et al. discloses the following of claim 16: the vascular system of claim 12, wherein the vascular device is releasably connected to the balloon (col. 6, lines 20-21).

Anderson et al. discloses the following of claim 25: a replacement valve comprising a support structure (4, 7, 8, 14) and a valve (9) attached thereto, the valve being substantially conical in configuration (see Figure 2) and having a proximal end (end near label 4), a distal end (end near label 3), and a proximal and distal opening (openings will be at the ends when the valve is open), the distal opening facing away from the longitudinal axis (straight axis through device) when the valve is in the closed position (flaps pointed out) and aligned with the longitudinal axis when the valve is in the open position (flaps folded down).

Anderson et al. discloses the following of claim 27: the replacement valve of claim 25, wherein the valve is attached to a distal end of the support structure (see Figure 2).

Anderson et al. discloses the following of claim 28: the replacement valve of claim 25, wherein the valve is offset with respect to the longitudinal axis of the support structure (see Figure 9, where a straight line through the valve will not be centered with the rest of the device).

Anderson et al. discloses the following of claim 30: the replacement valve of claim 25, wherein the support structure is in the form of a cylinder (see Figure 2).

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Flomenbilt et al. (US Pat. No. 5876434). Anderson et al. discloses the invention substantially as claimed, however, Anderson et al. does not disclose the use of shape memory material with exposure to body temperature to control the alterations of the device. Flomenbilt et al. teaches shape memory material and exposure to body temperature in col. 2, lines 37-65 and col. 4, line 66 through col. 5, line 15 for the purpose of causing the device to assume the necessary configuration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use shape memory material with exposure to body temperature in order to cause the device to assume the necessary configuration.

Claims 7, 17, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Wilson et al. (US Pat. No. 5876434). Anderson et al. discloses the invention substantially as claimed, however, Anderson et al. does not disclose the use of blood drainage openings. Wilson et al. teaches these openings in col. 2, lines 42-65 and col. 3, line 66 through col. 4, line 7 for the purpose of relieving excess pressure. Therefore, it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to use these openings in order to relieve excess pressure.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Duerig et al. (US Pat. No. 6503272). Anderson et al. discloses the invention substantially as claimed, however, Anderson et al. does not disclose the valve attached to the proximal end of the support structure. Duerig et al. teaches this valve position openings in col. 8, lines 20-45 for the purpose of best suiting a patient's blood flow configurations. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to put the valve in this position in order to best suit a patient's blood flow configurations.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754.. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger  
April 23, 2007

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**